Department of Pathology
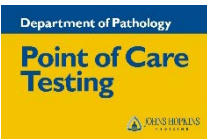**Point of Care Testing**
JOHNS HOPKINS

Xpert Xpress® SARS-CoV-2 Tests on the GeneXpert Xpress System: Initial Training and Competency

Date: _____   Site: _____   Operator Name: _____   JHED:_____

All new testing personnel must complete both pages of this form in entirety. The original must be maintained on the unit with staff competency records, and a copy must be provided to the POCT Office.
Only a POCC or Super User approved for training others in Molecular POCT may train new testing personnel to use the GeneXpert Xpress System.

Initial Training:

Competency Category	Performance Indicator	Assessment Tool	Criteria Met	Criteria Not Met	Remedial Action
			Trainer √		
eLearning	New testing personnel up-to-date on eLearning quiz *prior* to initial training **(Completion Date:_____)** - Understands requirement to complete eLearning and pass quiz on an annual basis.	Exam			
Reagent Stability and Storage	Maintains a working knowledge of different types of Test Kits and Control Storage, and Analyzer Requirements: - Records open dates on Test Kits and Controls. - States expiration date of consumables (Manufacturer's Expiration Date). - Does not use expired Test Kits, Controls, or consumables.	Exam			
QC Performance	Adheres to QC policies and procedures, including labeling of UTM/VTM transport vials, and PPE requirements. - Runs appropriate QC at defined frequency (minimum weekly, new lots and shipments, training, annually). - Demonstrates proper testing technique. - Correctly documents QC results, as applicable, for non-interfaced tests. - Understands troubleshooting for failed QC.	Direct observation Exam			
Specimen Collection	Adheres to procedure for collecting NP swabs and properly placing in UTM/VTM transport vials. - Properly labels UTM/VTM transport vials with two patient identifiers or patient label. - States bagging requirements for specimen transport. - Understands requirement to keep all tested and resulted patient specimens in a rack in the refrigerator.	Direct observation Exam			
Routine Patient Testing	Adheres to Patient Testing procedure, as outlined in POCTW044. - Does not process improperly labeled specimens, or those without the proper order in Epic. - Processes one specimen at a time, wearing proper PPE at all times. - States how to properly program the instrument and complete all testing steps.	Direct observation			
Limitations of Procedure	Interprets and evaluates test results in regards to test limitations (see POCTW044).	Direct observation Exam			
Documentation of Results	Evaluates and records test results appropriately. - For non-interfaced tests: Correctly completes the appropriate Patient Result Log. - For non-interfaced tests: Properly documents results manually in Epic. - For interfaced tests: Confirms posting of results to patient charts following test completion.	Direct observation Review of records			
Problem Solving Skills	Understands interpretation and corrective action for Invalid Test Results. Understands troubleshooting steps. - Follow on-screen instructions, or contact POCT Office as applicable. Knows POCT Office Contact Information (5-2645 M-F; POCT Consult on CORUS; POCTGroup email). - Understands Microbiology is 24/7 backup for testing.	Exam Direct Observation			
Safety	Wears proper PPE at all stages of testing (*double gloves, gown, N95 mask/face shield, or PAPR hood with HEPA filter*). Discards all testing materials in biohazard sharps and biohazard bins as indicated in POCTW044. Testing area is disinfected as directed in the policy at least once per day. - Understands how to complete all other maintenance as indicated on Maintenance Log.	Direct observation Exam			
Procedure review	Acknowledges ongoing competency requirements (annual successful completion of QC and pass eLearning quiz). Locates and reads the current version of the SOP (*POCTW044*).	Operator Acknowledgment	**Operator Initials:**		

Initial Competency:

Testing personnel must complete the appropriate log below, based on the type of cartridge available at the time of Initial Training and Competency.

SARS-CoV-2 Cartridges:

Date	Operator Initials	Instrument ID	Cartridge Serial Number (Last 4 Digits)	QC Level	Lot Number	SARS-CoV-2 Result	Results Acceptable (Y/N)	Comments
				Negative		RNA Detected RNA Not Detected Invalid	Yes No	
				Positive		RNA Detected RNA Not Detected Invalid	Yes No	

SARS-CoV-2/Flu/RSV and CoV-2/Flu/RSV plus Cartridges:

Date	Operator Initials	Instrument ID	Cartridge Serial Number (Last 4 Digits)	QC Level	Lot Number	SARS-CoV-2 Result	Flu-A Result	Flu-B Result	RSV Result	Results Acceptable (Y/N)	Comments
				Negative		RNA Detected RNA Not Detected Invalid	RNA Detected RNA Not Detected Invalid	RNA Detected RNA Not Detected Invalid	RNA Detected RNA Not Detected Invalid	Yes No	
				Positive		RNA Detected RNA Not Detected Invalid	RNA Detected RNA Not Detected Invalid	RNA Detected RNA Not Detected Invalid	RNA Detected RNA Not Detected Invalid	Yes No	

I have reviewed this checklist with the new operator and observed completion of QC. POCC/Trainer Initials signify this operator:

Is competent to perform patient testing with the Xpert Xpress SARS-CoV-2 Tests on the GeneXpert Xpress System _____

Requires retraining before performing patient testing with the Xpert Xpress SARS-CoV-2 Tests on the GeneXpert Xpress System _____

Operator signature: _____   Date: _____

Trainer signature: _____   Date: _____

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